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(54) **Processor-controlled angiographic injector device.**

(57) An angiographic injector device for use in x-ray photography for delivering contrast media to a patient at controlled rates and pressures. A processor elicits injection parameters from an operator or a pre-programmed injection module, and on the basis of the injection parameters, calculates appropriate control signals for use in a closed-loop servo system to actuate the plunger of a syringe containing the contrast media. Injection parameters include flow rate, volume, duration, pressure limit and rise/fall time of flow rate. The device also includes control circuits for inhibiting the injection device in response to a contrast media pressure limit, failure in the processor or injection control system, or upon reaching a predetermined volume of injected media. A mechanical stop member cooperates with the control circuit for blocking movement of the syringe plunger upon reaching the predetermined injected volume. Further, the device includes a self-test feature for checking the status of operational components thereof and a self-calibration feature for calibrating the servo system and position monitors. To improve reliability and to provide immunity from data corruption due to line power interruption, injection parameters are stored in battery-powered primary and secondary memories, and are compared and verified prior to an injection. To assist in coordinating an injection in synchronism with cardiac activity, the device monitors the ECG waveform of the patient's heart and injects a small bolus of contrast media at a given interval, such as the distolic interval. An interface also is provided for providing remote transfer of status and control information with the angiographic injector device.

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PROCESSOR-CONTROLLED ANGIOGRAPHIC INJECTOR DEVICE

Background of the Invention

This invention pertains to angiographic devices for injecting into a patient contrast media at a controlled rate and pressure during x-ray photography. More specifically, this invention is an improvement over commonly assigned, incorporated U.S. Patent No. 4,006,736, which improvement concerns automated control of such angiographic injector devices being responsive to input information supplied by an operator to develop control signals for automatically controlling the injection process.

An angiographic injector is useful for controlling the delivery rate, amount, duration, and pressure of contrast media, usually a liquid iodine solution, injected into a patient. Such devices are used in x-ray photography to enhance the contrast of the image obtained thereby. In a typical operation of such device, an operator loads the same with a certain amount of contrast media, connects a delivery tube extending from a fluid reservoir of the device to a catheter placed in the vascular system of a patient, and then actuates the device by forcing the media into the blood stream while exposing the patient to x-rays during the photographic process. Among other things, it is very important that the proper amount of contrast media, as well as the pressure and rate at which it is delivered, be controlled accurately for safe and desirable results.

One such angiographic injector device over which the present invention is an improvement is described in U.S. Patent No. 4,006,736 issued to Kranys et al, commonly owned by the assignee hereof. As with many other types of angiographic injector devices, this system is rather mechanical and although efficient, does not take advantage of certain potential automatic control and test features which can facilitate its use and reduce the likelihood of errors during its operation. As known, certain errors can be fatal or expose the patient to undue risks of harm.

As examples of potential capabilities under automated control, it is often desirable to provide multi-level injections during an x-ray photographing sequence. In this case, the contrast media is injected, for example, in step-wise changing flow rates and/or pressures. It is also desirable to provide multiphasic injections in which the programmed injection profile is delivered several times in succession under operator or remote control. Also, it may be desirable to automatically compute parameters involved in the injection of a specific amount of contrast media and to enable the size of the syringe to be changed without adversely affecting the operation of the injection and without requireing reprogramming. Such features are not known to exist with prior art devices. Moreover, certain mechanical control and electronic control features can be integrated to enhance reliability, such as by providing a mechanical stop member to prevent further movement of a syringe plunger when a predetermined amount of contrast media already has been injected.

Additionally, rather than requiring the operator to calculate flow rates and/or volumes, this can automatically be computed by a processor controlled system as a function of an injection parameter supplied to the system by the operator, whereupon the system itself would then calculate the corresponding pressure and control signals for delivery of the media. Still further, the use of a microporcessor in an angiographic injector device enables various programming verification steps not otherwise available. These are only a few automatic control features which are not known to exist with prior art systems.

In view of the foregoing, it is a primary objective of the present invention to provide a processor-controlled angiographic injector device for automatically delivering contrast media at controlled rates, pressures or volumes, which rates and pressures or volumes are automatically calculated on the basis of injection parameters supplied thereto by a user.

It is an additional objective of the present invention to provide safety and/or control features which limit the injection pressure and/or delivery of contrast media when certain limits are exceeded, such as a pressure limit of contrast media in the syringe.

It is yet a further objective of the present invention to provide a mechanical stop mechanism for mechanically preventing the plunger of a syringe from further movement when a given amount of contrast media has been injected, wherein the stop

position is automatically determined on the basis of injection information supplied to the device.

It is an additional objective of the present invention to interlock the operation of the mechanical stop mechanism and a plunger drive circuit of the injector device so that they alternate in operation to ensure that the drive circuit of the plunger does not operate until the drive circuit of the stop mechanism has completed its setting of the stop position.

Another objective of the present invention is to provide a multi-level injection sequence under processor control whereby the duration and/or injection rate and/or pressure may step-wise be changed during separate injection sequences, as well as to provide means for compensating the plunger drive rate and delivered pressure on the basis of syringe size during the injection process.

An additional objective of the present invention is to provide pre-programmed injection parameters stored in a memory which may conveniently be recalled instantly and to provide means for retaining the stored parameters in the memory in the event of power interruption to the device.

Another objective of the present invention is to provide a plurality of reliability features, such as parameter verification, self-calibration, and self-testing of the various components of the device in order to improve safety.

A yet further objective of the present invention is to provide means for providing messages from the angiographic injector to the operation, in human readable format.

Summary of the Invention

To attain the foregoing and additional objectives, the invention comprises a processor-controlled angiographic injector device including a pressure jacket for receiving a syringe containing liquid contrast media, contrast media drive means for forcing the media from the syringe, and processor control system for calculating injection control signals and for controlling the delivery of the contrast media. The processor control system is programmed to elicit injection parameters from an operator or from a pre-programmed storage module and, on the basis of the injection parameters, for calculating the necessary control signals for a closed-loop servo system which actuates the plunger of a syringe. The processor also determines position limits of plunger actuation and effects actuation of a mechanical stop member to block further movement of the plunger when a predetermined volume of media is injected. To improve reliability, actuation of motors for the mechanical stop member and the plunger drive are alternately enabled by a safety relay.

In alternative embodiments of the invention, a pre-programmed storage module is provided for storing routine injection parameters so that they can be instantly recalled. A hardware verification system comprising primary and secondary

memories for storing duplicates of injection parameters also is provided. The controller additionally provides multi-phasic injection sequences which involve step-wise changing of the injection parameters (e.g., rate, duration, and/or pressure) during an injection sequence.

Further, the angiographic injector device includes a watchdog circuit which monitors failures in the processor-controlled system, such as in the memories, and the processor itself, and in response to a failure, inhibits the plunger drive means. A self-check feature periodically performs diagnostic routines and a self-calibration feature re-calibrates the servo positioning system when there is a deviation from desired accuracy. To aid in certain types of x-ray photography, such as arteriography or ventriculography, an alternative embodiment of the device includes means for monitoring an ECG waveform and for injecting a small bolus of contrast media at a given rate and pressure during the diastolic interval. Moreover, the alternative embodiment includes an interface circuit for providing external digital communication for transferring either status and/or control information (e.g. injection parameters).

These and other embodiments, aspects, advantages and features of the invention will become apparent upon review of the succeeding disclosure taken in connection with the accompanying drawings. The invention, though, is pointed out particularly by the appended claims.

Brief Description of the Drawings

Figure 1A depicts a block circuit diagram of a preferred embodiment of the invention.

Figure 1B depicts a watchdog timer circuit of Figure 1A for monitoring CPU failures.

Figure 2 depicts circuit components of the servo amplifier of Figure 1.

Figure 3 depicts a functional block diagram of the servo control unit of Figure 1.

Figure 4 depicts a circuit diagram of the mechanical stop controller of the inventive angiographic device of Figure 1.

Figures 5A is a diagram of the mechanical stop mechanism which responds to the controller of Fig. 4 of the angiographic injector device.

Figure 5B depicts an arrangement for visually indicating a scaled volume of contrast media ejected from a syringe.

Figure 6 depicts the front control and display panel of Figure 1.

Figures 7A, 7B, 7C and 7D depict the sequence of the self-test and self-calibrating features under which the automated injector device goes.

Figures 8A, 8B, 8C and 8D show flow diagrams of the operation of the processor controlled injection procedures.

Detailed Description of Illustrative Embodiment

Referring to Figure 1A, primary functions of the automated angiographic injector device are controlled, monitored and executed by a central processing unit (CPU) 10 such as a commercially known Z80A microprocessor which includes a memory. The memory comprises a read only portion (ROM) such as a 2732 EPROM and a random access portion (RAM) such as a 4016 static NMOS RAM. Coupled to the CPU 10 is an I/O module 12 which, under control of the CPU 10, prompts the operator for certain input parameters and also alerts the operator of error conditions in the system. The I/O module is can posed of peripheral devices such as the Zilog Z80-PIO peripheral input/output controller. An indicator panel 14, and keyboard 16 provides operator/injector device interface. In practice, the panel 14 includes a flat sealed membrane to shield electrical switch contacts from contamination. A storage module 18 stores pre-programmed injection parameters which may be instantly recalled and supplied to the CPU 10 when a routine injection procedure is to be performed. The injection module 18 comprises two primary random access memories. Each memory contains a duplicate of the information of the other memory, and prior to an injection procedure, the contents thereof are compared for consistency. If inconsistent, the injection is inhibited.

A computer interface 20 provides external remote communication with the automated injector device and functions to transfer both status information and control information with the

device for remote operation and/or monitoring to provide communication compatability with various external devices. The interface 20 includes, but is not limited to, a standard universal asynchronous receive/transmit port connectible by way of a commercially known RS-232 serial channel or other parallel interface.

The contrast media to be injected into the patient is normally contained in a syringe, the plunger thereof being actuated to force the media therefrom into the vascular system of a patient through a catheter. The delivery rate and volume are normally derived from position signals indicative of the plunger position. Pressure is derived from current supplied to the motor. A servo control network 22 applies a conventional error signal to a servo system for controlling the position of the syringe plunger to control the flow rate and pressure of the contrast media. More specifically, the servo control network 22 supplies error signals to a servo amplifier 24 which energizes a conventional D.C. motor for controlling the position of the plunger.

Also provided for safety enhancement is a mechanical stop controller 26 which, under the control of the CPU 10 and an interlock safety relay 28, automatically positions a mechanical stop member (subsequently described) under control of the CPU 10 to mechanically stop further plunger movement thus prevening additional injection after the desired volume of contrast media has been injected. The safety relay 28 alternately enables the mechanical stop motor and the plunger motor so that one and only

one may be operative at a given time. This feature enhances reliability because it ensures that the mechanical stop fully reaches its appropriate position before it is possible to drive of the syringe plunger.

A watchdog circuit 30 monitors certain functions of the CPU 10 to effect shutdown of the system by inhibiting delivery of contrast media in the event of a failure or a fault. The watch-dog circuit, as shown in Figure 1B, consists of a retriggerable timer (such as a 74123 monostable multivibrator) which generates a pulse after a fixed time interval unless a strobe signal is received from a data selector 13 before the interval elapses. Under normal operating condition, the CPU 10 executes its control sequence and periodically outputs an address to the data selector 13 (such as 74154) which generates the strobe signal. If a CPU or memory failure occurs, the normal program sequence is interrupted, the data selector 13 is not addressed, the strobe signal is not generated, and the timer 11 is not retriggered. The resulting pulse from the timer automatically opens the safe relay, thereby removing power from the plunger and forcing the processor to execute a non-maskable interrupt (NMI). The NMI forces the CPU 10 to inform the user of a fault condition and then to halt.

Figure 2 depicts the servo amplifier 24 of Figure 1A. The servo amplifier provides power to move a drive plunger motor 40 under control of digital commands from the CPU 10. The servo amplifier 24 drives a plunger motor 40 which is driven by

filtered direct current derived from a series of pulse width modulated current pulses. To drive the plunger motor 40, a D.C. voltage source 42 supplies current to the motor 40 by feeding the respective collectors of transistors 46 and 56. To drive the plunger motor 40 in a forward direction, a position error detect circuit 50 switches on transistor 46 and a pulse-width modulating control circuit 52 delivers a series of enabling pulses to the field effect transistor (FET) 48.

The error detect circuit 76 generates follows a position error signal from the servo control 22 via a conductor 54. During forward driving of the plunger motor 40, a corresponding set of transistors 56 and 58 is switched off. This allows d.c. current pulses to flow in a forward direction through the plunger motor 40.

To drive the plunger motor 40 in a reverse direction, the error detect circuit 50 switches on transistor 56 and the pulse width modulating circuit 52 pulses the field effect transistor 58. In this fashion, the plunger motor 40 is driven in the reverse direction by the supply of d.c. current pulses in an opposite direction therethrough. Instead of employing FETs 48 and 58, a set of silicon controlled rectilius also can be used.

The position error signal supplied to the servo amplifier 24 over the conductor 54 indicates whether the plunger is ahead of or behind the desired position, and also controls the drive transistors 46, 56, 48 and 58 in an appropriate fashion so that the plunger motor 40 causes the plunger (not shown) of the

syringe to track the desired position to maintain the appropriate flow rate, pressure and/or duration. The position error signal is proportional to the magnitude of the difference between the actual position of the plunger and the desired position of the plunger. As the difference increases, so does the width of the drive pulses supplied by the pulse-width modulating circuit 52 to the drive transistors 58 and 48. Thus, when the position error signal is large, the average current supplied to the plunger motor also increases.

The servo amplifier 24 also includes a pressure limit circuit 60 which functions to inhibit the pulse-width modulating circuit 52 and shut down the drive current pulses supplied to the plunger motor 40. The circuit 60 constitutes a control circuit which informs the servo control when the pressure in the syringe exceeds a given set point established by the processor 10. It does so by monitoring motor current which is proportional to the fluid pressure, and operates to reduce the motor velocity of the plunger motor 40 by cutting the duty cycle of pulse-width modulated current pulses when the pressure exceeds a preset limit. The injector device has pressure input means to set and/or display the pressure limit in conventional units of PSI, KPA, KG or ATU. A switch is also provided to select and/or display the selected unit.

Under normal conditions, when the pressure limit has not been exceeded, the servo amplifier 24 causes the plunger position to follow the position command established by the

processor 10. A digital-to-analog converter device 74 in the servo control portion of the system sets the pressure limit command. When actual pressure exceeds the programmed pressure limit, the pressure limit circuit 60 asserts a pressure limit indication signal 64 which informs the CPU 10 to stop changing the position command signal. The pressure limit command signal is supplied to the servo amplifier 24 via conductor 62. When the pressure limit signal 64 is no longer present, the CPU 10 retakes control by resuming the transmission of position command signals starting from the known plunger position. The plunger position, derived from a rotary potentiometer or optical encoder, is monitored by a plunger position circuit 66, also embodied in the servo amplifier 24. The output of the plunger position circuit 66 is supplied to the servo control 22 via a conductor 68.

Figure 3 depicts a servo control circuit 22 in greater detail. The servo control circuit 22 provides an interface between the digital and analog components of the angiographic device. The CPU 10 provides digital position command signals via conductor 70 to a driver bidirectional buffer 72. The digital position command signals are eventually converted to an analog signal by a digital-to-analog converter 74 which are compared by a comparison network in the error circuit 76 which then appears as position error signal on conductor 54. As previously indicated, the plunger position error signal on conductor 54 is supplied to the servo amplifier 24 of Fig. 2.

To perform control and monitoring functions, an analog multiplexer 75, under control of the CPU 10 or a clocking signal, selectively conveys analog output signals from the control D/A circuit 74 or error circuit 76 to an A/D converter 77. The A/D converter 77 converts these signals to digital form and then, in turn, passes it to the CPU 10. The CPU 10 uses these digital signals to perform such functions as calibration, self-testing, and servo control. These functions are subsequently described.

The servo control circuit 22 also regulates the operation of the interlocked mechanical stop/plunger relay in the servo amplifier circuit 24 and the mechanical stop controller circuit 26. A peripheral input/output device 78 in the servo control circuit 22 provides means for transferring status and control signals to alter the operation of the servo amplifier circuit 24 and the mechanical stop controller 26. With respect to the interlocked mechanical stop/plunger relay operation, the input/output circuit 78 removes the plunger ARM signal via conductor 80 when the plunger reaches a predetermined position as determined by the CPU 10 and monitored by the plunger position circuit 66 (Figure 2). An ARM signal supplied over the conductor 80 is conveyed to the mechanical stop controller circuit 26 to actuate a mechanical stop drive motor which inhibits further plunger movement. This feature also will be subsequently described. The servo control circuit 22 also generates pressure command signals and monitors the pressure limit.

Figure 4 depicts the mechanical stop controller 26 wherein a mechanical stop motor 90 couples a mechanical stop member to actuate it against the plunger drive mechanism to block movements thereof when a predetermined calculated volume of contrast media has been injected.

Similarly to the plunger drive motor 40 of Figure 2, in a preferred embodiment, the mechanical stop motor 90 turns a ball screw to drive a mechanical stop plate forward. The drive command is given to drive the mechanical stop motor 90 at full speed until the mechanical stop position indicator on the mechanical stop mechanism indicates that desired position has been attained. This is accomplished by converting a potentiometer position signal supplied over conductor 111 from the stop mechanism to a digital value via an analog/digital converter. When the position signal indicates engagement of the stop plate, the drive command is removed.

Figure 5A depicts an illustrative mechanical assembly for driving the piston of a syringe containing contrast media. As seen, a movable drive plate 200 actuates a piston 202 of a syringe 204 by way of a shaft 206. Although shown in spaced-apart relation, the piston 202 connects to a spring clip 208 when engaged therewith. The spring clip 208 is fastened to the end of the shaft 206. A plunger drive motor (not shown) corresponding to the motor 40 (Fig. 4) of the controller actuates the shaft 206 through the plunger plate 200. Linear movement of the plunger plate is guided by a guide rod 210.

As previously indicated, a mechanical stop prevents further movement of the drive shaft when a fixed amount of contrast media has been injected. To accomplish this task, a stop member in the form of a plate 212, is prepositioned prior to an injection. Prepositioning is done by a stop motor 214 (corresponding to motor 90 of Fig. 4) under control of the CPU 10. Conventional position transducers in the form of resistive potentiometers supply position information of the stop member 212 to the CPU 10 through an A/D converter.

Actuation of the stop member 212 is done by rotation of shaft 216 having threads mechanically coupled to a bore that is journalled through a bushing 218 held against the stop plate 212 by a nut 220. To rotate the shaft 216, motor 214, when energized, turns a grooved, flexible drive belt 222, which in turn, rotates a drive pulley 224. The pulley 224 connects to the shaft 216.

Figure 5B depicts a system for visually indicating the volume of contrast media injected from a syringe by utilizing different scales. Each scale corresponds to a syringe of a particular size, and the "active" scale is indicated by the appropriate light being energized. A face card 226 contains three separate scales 228, 230, and 232 of different units corresponding to incremental units of media in a syringe 204. Syringes of different diameters yield different units of media for the same linear movement of the plunger 202. To visually indicate which unit applies to a particular syringe, LED indicators 234, 236 and

238 are provied. One of these indicators is activated by a switch to show which scale is active, in which case, a needle 240 carried by arm 242 indicates relative volume injected. The arm 242 connects to the stop plate 212 while the face card 226 connects to the drive plate 200.

As previously indicated, the double-throw, double-pole operation of the relay 28 (Fig. 1A) energizes either the drive motor 90 (Fig. 4) or the plunger drive motor 40, but not both simultaneously. The mechanical stop motor 90 functions similarly to the plunger motor 40 of Figure 2, in that it includes a set of field effect transistors 100, 102, 104 and 106 which are energized to drive the mechanical stop motor 90 in a forward and/or reverse direction. Direction is controlled by a direction circuit 109 in response to a signal from the servo control 22 supplied via the conductor 108. The mechanical limit of the mechanical stop motor is controlled by a mechanical stop position circuit 110 which responds to a limit switch when the stop plate reaches a forward-most position or rearward-most position.

The CPU 10 controls the system using a microprocessor and associated program for monitoring or eliciting input information (e.g. injection parameters) supplied by an operator and then develops command information to control the injector device. The CPU 10 communicates with the I/O module 12 which interfaces external switches on the front control panel of the system.

The watchdog circuit 30 implements an active system for inhibiting injection of contrast media in the event of a

microprocessor failure. The circuit 30 includes a re-settable timer which opens the safety relay 44 after a predetermined time period unless the CPU 10 actively resets it, thus allowing this cycle to repeat. Thus, if the CPU 10 fails, the safety relay 44 will be deactivated without further operation of the CPU 10.

The I/O module 12 monitors a manual signal supplied by the operator via a manual start switch 12 or an event signal from an external device supplied over the conductor 114. As previously indicated, the automated angiographic injector device may respond to certain cardiac events by monitoring an ECG signal thereby to actuate, or start an injection, at a predetermined time instance during an ECG cycle. This is done using well known techniques by the external event signal, and is particularly useful during certain cardiac studies.

The control/display panel 14 provides user/device interface for inputting and displaying injection parameters, such as syringe size, flow rate, volume, duration, pressure limit, or rise/fall time. This information can be prompted by the CPU 10 and entered by the operator. The entries are echoed back to the operator for a visual verification on a display of the panel 14. In physical construction, the panel 14 comprises a sealed membrane switch panel that is impervious to fluid spills and wipes clean without damage to switches contained underneath. Prior to an injection, the injection parameters are displayed and verified by an operator. Verification enables, e.g. arms, the injector device, and is preferably accomplished manually by depressing a

contact switch associated with each injection parameter. After an injection, the actual values of flow, bolume, etc. can be displayed so that teh operator may confirm an effective or safe injection.

A pre-programmed injection module 18 provides non-volatile storage of injection parameters. Specific routine angiographic procedures require established flow rates, volumes, pressures and linear rise/fall time, but once these parameters are established, set-up of the angiographic device becomes routine. As an added convenience, these parameters can be stored in the pre-programmed injection module 18 so that an injection can proceed immediately after arming the system without the necessity to re-enter the injection parameters. To enhance reliability of the pre-programmed injection module 18, the stored injection parameters are verified by duplicating the values thereof in an auxiliary memory. Thus, the pre-programmed injection module preferably comprises a primary and a secondary random access memory for storing duplicates of the injection parameters and, prior to an injection procedure, the CPU 10 compares the contents of both memories to verify the parameters. Both memories are maintained with batteries when power is shut down thereby achieving non-volatility.

Figure 6 depicts a preferred arrangement of the front panel 14 of Figure 1 for providing an indication of injection parameters entered, confirmed and/or displayed in the device, and for providing an indication of control/injection parameters under

which an injection had taken place. The front panel 14 preferably comprises a flat, sealed membrane covering switches located beneath the flexible membrane. This structure seals the switches from possible contamination from an external environment.

The front panel 14 includes various sections to facilitate entry of injection parameters and for displaying the status of an injector procedure. Display and entry of information is preferably accomplished in human readable format. Specifically, the front panel 14 includes a sentinel 130 which includes an alphanumeric display section 132. The display section 132 displays, among others, alphabetical and numeric information which is entered into the injector device by way of an alphanumeric keypad section 134. The keypad 134 enables entry of both numeric and character information in a conventional manner. During entry, the information is displayed on the sentinel display section 132.

The front panel also includes a dual function control and display section including an individual input pad 142 for entering and/or confirming, among other parameters, a rise/fall time of flow of contrast media. In operation, once the switch pad 144 is depressed and the desired rise/fall injection parameter is entered into the device, the specific rise/fall injection parameter is displayed in the display section 146. Similarly, a desired flow rate also can be programmed into the injection device. This injection parameter is displayed in a flow rate display 148 and entered into the device by switch input

pad 150. The units of flow rate can be entered or displayed in milliliters per second, milliliters per minute, or milliliters per hour under control of a switch pade 152.

The dureation of an injection can be entered by depressing the switch pad 154 and then pressing "number" keys on keypad 134. Injection duration is displayed in a display portion 156. Any two of the three parameters, flow, volume, duration, may be entered in any order, and the third then automatically is calculated.

The volume of contrast media to be injected during an injection sequence is displayed in display 158 and is entered and/or confirmed by the switch pad 160. Similarly, the pressure at which the contrast media is to be injected is displayed and/or entered, respectively, by display 162 and switch pad 164. Similarly, x-ray photo delay from the time an injection sequence begins is displayed on display 166 and is entered with switch pad 168 and numerical keypad 134.

To facilitate entry of the injection parameters, the CPU 10 effects flashing of indicator lights located above the switch pads 144, 150, 152, 154, 160, 164, and 168. For example, when the CPU 10 prompts the operator to enter the rise/fall injection parameter, an indicator light above the switch pad 144 flashes. When the appropriate value has been entered and is displayed correctly in the display 146, the switch pad 150 is depressed by the operator, whereupon display 146 ceases to flash and stays lit, while the indicator light over the switch pad 150

begins flashing. The flashing sequence advances to the next injection parameter to be entered as each parameter is entered.

If a processor-recognizable parameter is not entered, the CPU 10 effects generation of an alarm, such as an audible beep and/or error message on display 132. Further, the CPU 10 will prevent further entry or arming of the device until the error has been corrected. As an example, entry of an injection volume that is greater than the syringe size will cause an error. The panel 14 also has a contact switch for clearing the contents of any parameter or information displayed or entered into the injector device.

The front panel 14 further includes an arming section 170 for selecting a single phase or a multi-phase injection sequence. In order to recall routine injection parameters or to store a set of injection parameters, a program section 172 is provided. In operation, once a set of injection parameters is loaded into the device and displayed in the various parameter sections, an identification tag can be generated by way of the keypad 134, displayed in the sentinel 132, and stored in non-volatile memory by depressing the store switch 174. One or more numbers or words, or alphanumeric combinations, can be used to identify a prestored set of injection parameters. The set of injection parameters then is stored in a storage module under the name or number which appears in the sentinel 132 when stored. That same information can be quickly recalled by entering the

name or number associated with the previously stored set of injection parameters by depressing recall switch 176.

Then, before the injector can be armed for performing an injection, the operator is required to depress each of the switch pads 144, 150, 152, 154, 160, 164 and 168, to verify the accuracy of teh injection parameters being displayed.

During a multi-phasic injection sequence, a number of injections may be performed without disarming the machine after delivery of the programmed injection volume. Each depression of the main start switch 112 will deliver the same volume until insufficient volume remains in the syringe. A switch pad 178 in the arming section activates the device for a multi-phasic injection sequence. A level control section 182 indicates the number of levels in a single phase or multi-phasic injection sequence. The specific level may be incremented or decremented by way of switch pads 184 and 186 and parameters for each level are entered on switch pads 144, 150, 152, 154, 160, 164, and 168. During a single phase injection, the rise/fall time, flow rate, vlume, and pressure for each level are delivered until all levels (up to 9) are completed or the injection is terminated. During multi-phasic injections, all levels are delivered in continuous sequence unit the injection is complete. Each time the start switch 112 is pressed, the same injection is delivered without first rearming the machine via multi-arm keypad 178.

The central processing unit 10 also provides a self-calibration and a self test feature. Self-calibration allows

proper servicing of critical analog/digital and digital/analog converters in the system. Upon calling up of appropriate software routines, the processor commands a digital/analog converter 74 to transmit a corresponding analog value, which is then switched through an appropriate analog/digital converter 74. The converted value is then compared with the original digital value thereby to allow adjustment of gain and offsets in the servo control system.

The injector allows the user to enter a syringe size which is used to automatically adjust internal machine parameters to deliver the programmed flows, volumes, and pressures. Syringe size entry is made by answering questions posed by the sentinel display 132 although automatic detection of size may be accomplished by means of mechanical switches located behind the turret assembly.

Likewise, a self-test feature of the invention embodies software routines executed by the central processor 10 which initiates checks of the electrical components, such as the memory, address and data busses, device decoding and checks the accuracy of the data conversion hardware. These functions are accomplished by conventional hardware and specialized software routines, the latter being described in the flow charts of Figures 7A, 7B, 7C and 7D. If failures are detected by CPU 10, an appropriate diagnostic message appears on sentinel display 132 to aid in repairing the machine.

Figures 8A, 8B, 8C and 8D are flow diagrams showing the general operational sequence of the automated injector device for performing an injection as described above.

In view of the foregoing disclosure, it is seen that the specified advantages are obtained by providing automated control of an angiographic injector device. The disclosure hereof is illustrative and is not intended to limit the scope of the invention. Several modifications, changes and adaptations can be made by those skilled in the art without departing from the scope of the invention. For example, the data acquisition modules essentially comprises analog-to-digital and digital-to-analog converters, but are not limited to the same. These may be substituted by other types of data acquisition units to obtain information to provide the control of duration, flow rate and pressure of contrast media. Likewise, a closed-loop servo control system is shown, but the invention may be practiced with other types of control systems. Accordingly, it is the intent of each inventor to include all such modifications as may come within the true scope of the invention which is defined by the appended claims.

I Claim:

1. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of said media through said discharge port,

receiving means for receiving at least one injection control parameter, and

processor control means for generating at least one injection control signal as a function of said at least one injection parameter supplied thereto and for supplying said control signal to said drive means thereby to effect controlled discharge of said media.

2. An angiographic injector device as recited in claim 1, wherein said drive means and control means comprise a closed-loop servo system responsive to a processor position command signal produced by said processor control means, and said injector device further comprising:

pressure limit means responsive to a pre-established pressure limit signal for inhibiting the responsiveness of said servo system to said position command signal when the pressure in said reservoir exceeds said pre-established limit.

3. An angiographic injector device as recited in claim 2, wherein said pressure limit means includes means to receive said pre-established pressure limit signal in units of PSI, KPA, KG, or ATU and said angiographic injector device further includes switch means for selecting one of said units indicative of said pre-established pressure limit signal.

4. An angiographic injector device as recited in claim 2, wherein said reservoir comprises a syringe having a piston for forcing media through the discharge port thereof, said drive means comprises a d.c. servo motor operatively connected to said piston, and said control means includes means for supplying to said d.c. motor a d.c. current derived from a pulse-width-modulated drive current having duty cycle that is proportional to the difference between the actual and the desired positions of said piston during an injection.

5. An angiographic injector device as recited in claim 4, further including mechanical stop controller means responsive to a pre-established forward limit of said piston to inhibit said drive means from discharging media from said syringe, said forward limit being determined by said processor control means.

6. An angiographic injector device as recited in claim 5, wherein said mechanical stop controller means comprises a stop member and a d.c. stop motor operatively connected to said stop member, means for monitoring the position of said piston, means for producing a stop command signal when the position of said piston reaches said forward limit, and means responsive to said

stop command signal to actuate said stop motor which, in turn, advances said stop member to mechanically prevent forward movement of said piston.

7. An angiographic injector device as recited in claim 6, wherein said processor control means includes means for establishing said pre-established forward limit of said stop member in dependence on the value of an injection parameter supplied thereto.

8. An angiographic injector device as recited in claim 7, further including safety relay means for alternatively enabling one of said drive means and said mechanical stop controller means thereby to prevent movement of said drive means while said mechanical stop controller is actuated.

9. An angiographic injector device as recited in claim 8, further comprising an indicator light for visually indicating the position of said mechanical stop member and a second indicator light corresponding to the position of said piston relative to said first indicator light.

10. An angiographic injector device as recited in claim 1, further comprising:

watchdog means for monitoring an operational condition of said processor control means and for inhibiting said drive means in response to a failure of said processor control means.

11. An angiographic injector device as recited in claim 10, wherein said watchdog means comprises resettable timer means responsive to a reset signal for producing a shut-down

signal after a predetermined time interval, and said processor control means includes means for periodically producing said re-set signal whereby to inhibit passively said drive means in the event of failure of said processor control means.

12. An angiographic injector device as recited in claim 11, wherein said processor control means includes means for eliciting at least one injection parameter from an operator of said injector device thereby to facilitate use thereof.

13. An angiographic injector device as recited in claim 12, wherein said at least one injection parameter includes at least one parameter selected from a group including flow rate of contrast media, volume of contrast media, duration of an in-jection, pressure limit of said contrast media, x-ray photo de-lay, inject delay and flow rise/fall time of pressure of contrast media.

14. An angiographic device as recited in claim 13, wherein said receiving means comprises a sealed, flat membrane control panel having individual input pads associated with each of said at least one injection parameter, each said input pad being operable for inputting into said control means an associ-ated injection parameter.

15. An angiographic device as recited in claim 14, wherein said processor control means further includes arming means responsive to the actuation of each of said at least one input pad for enabling said drive means and for inhibiting said

drive means when any one of said at least one said input pad is not actuated.

16. An angiographic injector device as recited in claim 13, further comprising:

primary memory means for storing said at least one injection parameter,

secondary memory means for storing a duplicate of the contents of said at least one injection parameter, and

parameter verification means for comparing the injection parameters of said primary and secondary means and for inhibiting said drive means when a mismatch in stored injection parameters occurs.

17. An angiographic injector device as recited in claim 13, further comprising memory means for storing a set injection parameters, means for producing an identification tag for each set of of said at least one injection parameters and for storing said tag with said set in said memory means, recall means responsive to a given tag for recalling from said memory means an associated set of injection parameters and for supplying said recalled set of injection parameters to said receiving means thereby to enable quick recall of routine sets of injection parameters without operator input prior to an injection.

18. An angiographic injector device as recited in claim 17, further including means for recalling and sequencing through each of said recalled injection parameters of a given set

and for eliciting information to amend a particular injection parameter.

19. An angiographic injector device as recited in claim 17, further including means for verifying each of said recalled input parameters prior to an injection.

20. An angiographic injector device as recited in claim 19, wherein said means for verifying comprises a manual switch associated with each of said at least one injection parameter.

21. An angiographic injector device as recited in claim 19, wherein said means for verifying comprises redundant memories for storing each of said injection parameters, means for comparing the contents of said injection parameter stored in said redundant memories, and means for disabling said injector device or alerting the operator in the event of a difference in said comparison of data between said redundant memories.

22. An angiographic injector device as recited in claim 21, wherein each of said redundant memories comprises a random access memory powered by a separate battery.

23. An angiographic injector device as recited in claim 16, wherein said primary and secondary memory means includes means for retaining said injection parameters in the absence of power to said injector device.

24. An angiographic injector device as recited in claim 1, further comprising:

interface means connected to said processor control means for transferring status information or an injection parameter with said injector device.

25. An angiographic injector device as recited in claim 24, wherein said interface means includes a universal asynchronous receive/transmit port for providing communication with an external device.

26. An angiographic injector device as recited in claim 1, wherein said control means includes multi-level injection control means for sequentially changing a given set of injection parameters during an injection.

27. An angiographic injector device as recited in claim 26, further including means for pre-establishing a rise/fall time of pressure level of said contrast media between successive phases of a multi-phasic injection sequence.

28. An angiographic injector device as recited in claim 1, further comprising:

self-calibration means including means for producing a test command signal to position said drive means at a test position, means for monitoring said drive means to detect the actual position thereof, means for comparing the test position with the actual position, and means for re-calibrating said drive means on the basis of said comparison.

29. An angiographic injector device as recited in claim 1, further including:

self-test means for automatically checking the accuracy of said control means and for producing an indication of a predetermined deviation from a desired accuracy and for inhibiting an injection in response thereto.

30. An angiographic injector device as recited in claim 29, wherein said self-test means comprises means for checking the operational status of said processor control means and said memory means.

31. An angiographic injector device as recited in claim 30, wherein said self-test means comprises means for executing instructions of said processor control means using test data and means for checking the results of each said executed instruction with a pre-established correct result.

32. An angiographic injector device as recited in claim 30, wherein said self-test means comprises means for writing known data in said memory means, means for reading back said known data written to said memory means, and means for comparing the read back data and the known data thereby to check the operational status of said memory means.

33. An angiographic injector device as recited in claim 30, wherein said memory means comprises a read only memory and said self-test comprises check means for verifying the contents of said read only memory.

34. An angiographic injector device as recited in claim 30, wherein said self-test means further comprises analog-to-digital and digital-to-analog testing means for checking the

accuracy of sensors, A/D converters and D/A converters of said injector device.

35. An angiographic injector device as recited in claim 30, wherein said self-test means sends a digital word to be converted to an analog signal to a digital-to-analog converter, and means for verifying the accuracy of said digital- to-analog converter on the basis of said transmitted information.

36. An angiographic injector device as recited in claim 34, wherein said self-test means generates and transmits a calibrated analog signal to an A/D converter and means for verifying the accuracy of the digital signal converted by said A/D converter.

37. An angiographic injector device as recited in claim 34, wherein said self-test means further comprises means for checking said pressure limit means.

38. An angiographic injector device as recited in claim 30, wherein said self-test means further comprises means for monitoring current supplied to said drive means on the basis of a calibrated controlled command current setting thereby to verify the operation of said drive means.

39. An angiographic injection device as recited in claim 1, wherein said control means further includes means for monitoring an ECG waveform representative of a cardiac cycle of the patient, and means for automatically effecting injection of a given quantity of media at a controlled rate during a given time interval of said cardiac cycle thereby to facilitate x-ray photography that is synchronized with said ECG waveform.

40. An angiographic injection device as recited in claim 1, wherein said receiving means further includes a flat, sealed membrane control panel including at least one input pad for each of said at least one injection parameter, said input pads being operable for entering said injection parameter.

41. An angiographic injector device as recited in claim 1, wherein said receiving means comprises a sealed, flat membrane control panel having a human readable format section to display operator inputs and to indicate output information pertaining to the injector device, a dual function control and display panel section for entering and displaying injection parameters, a numerical keypad section for entering alpha numeric information, a pre-programmed injection section for storing pre-established injection parameters, and an arming control section for enabling said drive means in response to information stored in said injection device and operator input.

42. An angiographic injector device as recited in claim 41, wherein said dual function control and display panel section includes means for clearing said display panel section and said human readable format section of information.

43. An angiographic injector device as recited in claim 41, further comprising a multi-phasic injection control section for receiving at least two sets of injection control parameters, and means for successively effecting injection in accordance with each set of injection control parameters.

44. An angiographic injector device as recited in claim 41, wherein said control means comprises means for eliciting from an operator a number of injection parameters, and said dual function control and display panel section comprises an indicator light associated with each said injection parameter, means operable during elicitation of each said input parameter for effecting flashing of said indicator light for alerting the operator of a particular injection parameter to be entered, and means for terminating said flashing when the injection parameter has been entered and for effecting flashing of a next successive indicator light associated with a next successive input parameter is to be entered by the operator.

45. An angiographic injector device as recited in claim 44, wherein said control means further comprises means for recognizing errors of an injection parameter entered by an operator, and means for generating an audible alert signal upon recognition of said error.

46. An angiographic injector device as recited in claim 1, wherein said reservior comprises a syringe having a plurality of scales disposed on a side wall thereof and an indicator light for indicating a selected scale whereby to enable visual observation of volume injected during an injection procedure.

47. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of said media through said discharge port,

control means connected to the drive means for regulating the discharge of said contrast media, said control means including at least one input pad associated with an injection parameter for controlling the discharge of said contrast media.

48. An angiographic injector device as recited in claim 47, wherein said at least one input pad and associated injection parameter is selected from a group of parameters including rise/fall time of pressure of contrast media, flow rate of contrast media, injection duration, volume of contrast media to be injected, pressure of said contrast media during injection, delay time from initial injection of x-ray photography, and delay time of injection from initiation of injection sequences.

49. An angiographic injector for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of said contrast media through said discharge port, and

control means for regulating the discharge of said contrast media, said control means comprising a control and display panel for indicating at least one injection parameter, said at least injection parameter being selected from the group of flow rate of contrast media, injection duration, volume of contrast media to be injected, pressure of said contrast media during injection, delay time of x-ray photography after initiation of injection, and delay time of injection from initiation of injection sequence,

said angiographic injector device further including switch means effective to cause said injector device to indicate the value of said at least one injection parameter which is set by an operator when placed in a first position, and the actual value of said at least one injection parameter after an injection is completed when placed in a second position.

50. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of said media through said discharge port,

control means for regulating the discharge of said contrast media, said control means further including a flat, sealed membrane control panel including human readable format for

displaying operator inputs and machine outputs of at least one injection parameter, a dual function control and display panel for displaying injection parameters, a numerical keypad section for inputting information including injection parameters, a preprogrammed injection section for storing a set of injection parameters and for providing pre-stored sets of injection parameters upon recall, and an arming control section for arming said injection device in response to a predetermined condition.

51. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for hold a reservoir containing contrast media and including a discharge port through which a the media is discharged,

drive means for effecting discharge of said media through said discharge port,

control means for regulating the discharge of said contrast media, said control means further including means for preprogramming the operation of said injector device including means for saving at least one injection parameter and means for recalling said at least one injection parameter.

52. A method for performing an injection using an angiographic injector device which includes means for holding a reservoir containing contrast media which includes a discharge port through which the media is discharged,

drive means for effecting discharge of said contrast media through the discharge port,

control means for regulating the discharge of said discharge media, said control means inlcuding meory means for storing injection parameters, means for displaying said injection parameters, memans for verifying said injection parameters, and means for arming said injection device in response to the verification, said method comprising the steps of:

recalling from said memory means a pre-stored set of injection parameters by entering an I.D. tag,

displaying said recalled set of injection parameters together with said I.D. tag,

verifying each of said injection parameters in said set, and

arming said injector device upon verification of each said injection parameter.

53. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of the contrast media through the discharge port, and

control means for regulating the discharge of said contrast media, said control means further including mechanical stop means for stopping said drive means, and means for automatically pre-positioning said mechanical stop means to inhibit said drive means after a predetermined volume of contrast media has been injected.

54. An angiographic injector device as recited in claim 53, wherein said reservoir comprises a syringe including a piston, said drive means includes means for engaging the piston of the syringe, said mechanical stop means comprises a movable mechanical barrier disposed in the path of said drive means for inhibiting further movement thereof when pre-positioned at a predetermined position, which position is determined by said control means.

55. An angiographic injector device as recited in claim 54, including means for determinging the position of said movable mechanical barrier as the function of an injection parameter supplied by an operator.

56. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of said media through the discharge port,

control means for regulating the discharge of said contrast media, said control means including means for effecting multi-phasic injection sequences wherein, during each injection phase, the injection of contrast media is controlled according to individual sets of injection parameters successively supplied to said control means.

57. An angiographic injector device as recited in claim 56, wherein between each phase of said multi-phasic injection, the rise/fall magnitude of pressure of contrast media is controlled at a predetermined level.

58. An angiographic injector device as recited in claim 57, further including means for verifying each parameter of a set of injection parameters between successive phases of a multi-phasic injection sequence.

59. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of said contrast media through the discharge port, and

control means for regulating the discharge of said contrast media, said control means further including self-test means for monitoring an operational state of said angiographic injector device and for producing an error signal in the event that a fault is detected.

60. An angiographic injector device as recited in claim 59 including memory means for storing information pertaining to and injection and A/D and D/A converters for interfacing analog and digital control and status signals, wherein said monitored states include the operational state of

said processor, said memory, and said A/D and D/A convertors.

61. An angiographic injector device as recited in claim 59, wherein said monitored states includes excessive pressure of said contrast media during an injection, excessive current drawn by said drive means, excessive positional error of said drive means, and said control means is responsive to inhibit said injector device in the event that said operational states are excessive.

62. An angiographic injector device for injecting contrast media into the vascular system of a patient, said device comprising:

means for holding a reservoir containing contrast media and including a discharge port through which the media is discharged,

drive means for effecting discharge of said media through the discharge port, and

control means for regulating the discharge of said contrast media, said control means further including computer interface means for providing external communication with said angiographic injector device.

63. An angiographic injector device as recited in claim 62, wherein said computer interface means comprises a data channel for allowing external communication with said external device for transferring information including control and status information.

64. An angiographic injector device as recited in claim 63, wherein said external computer interface comprises a universal asynchronous receiver/transmit port.

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FIG. 1A

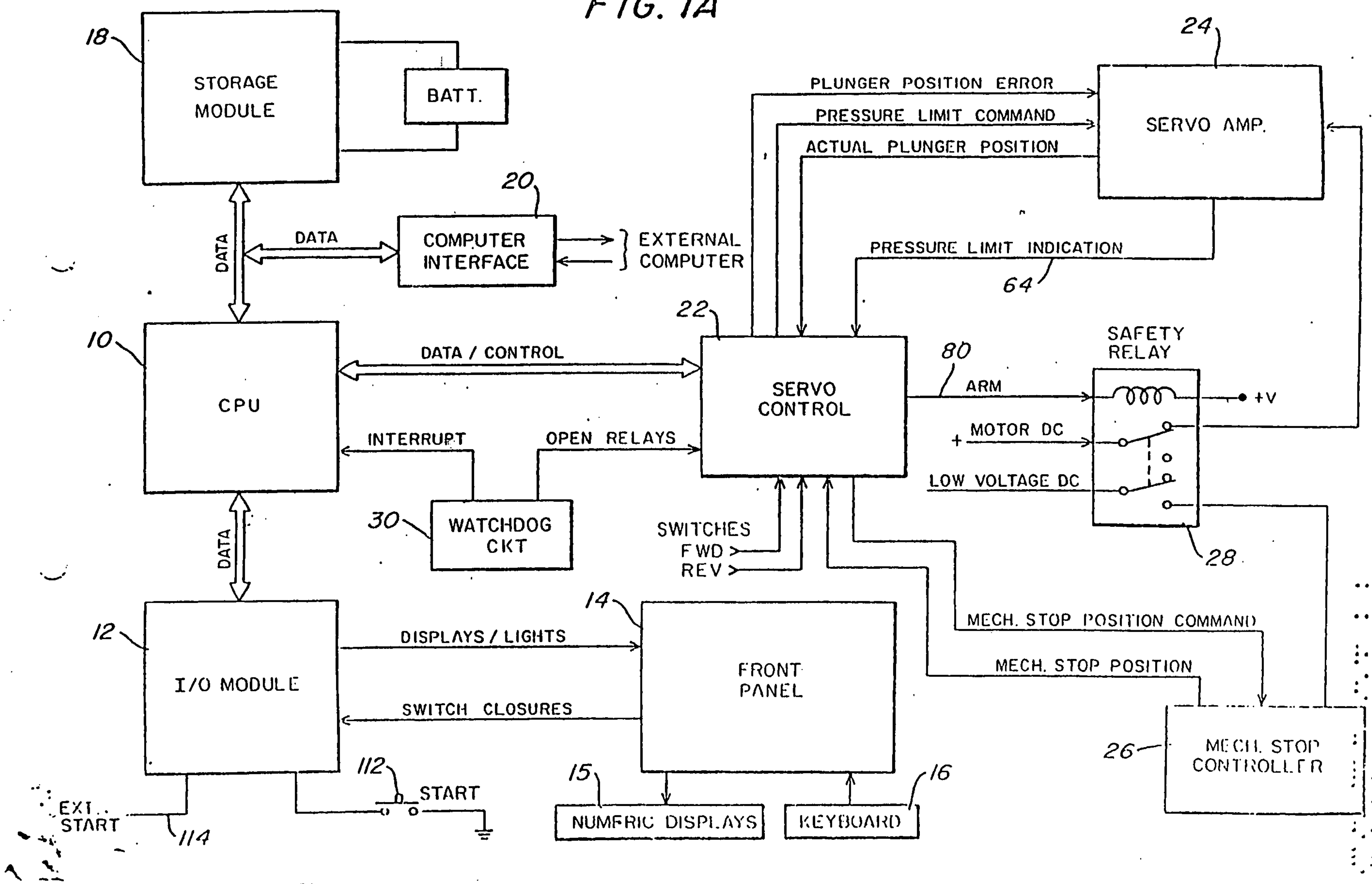
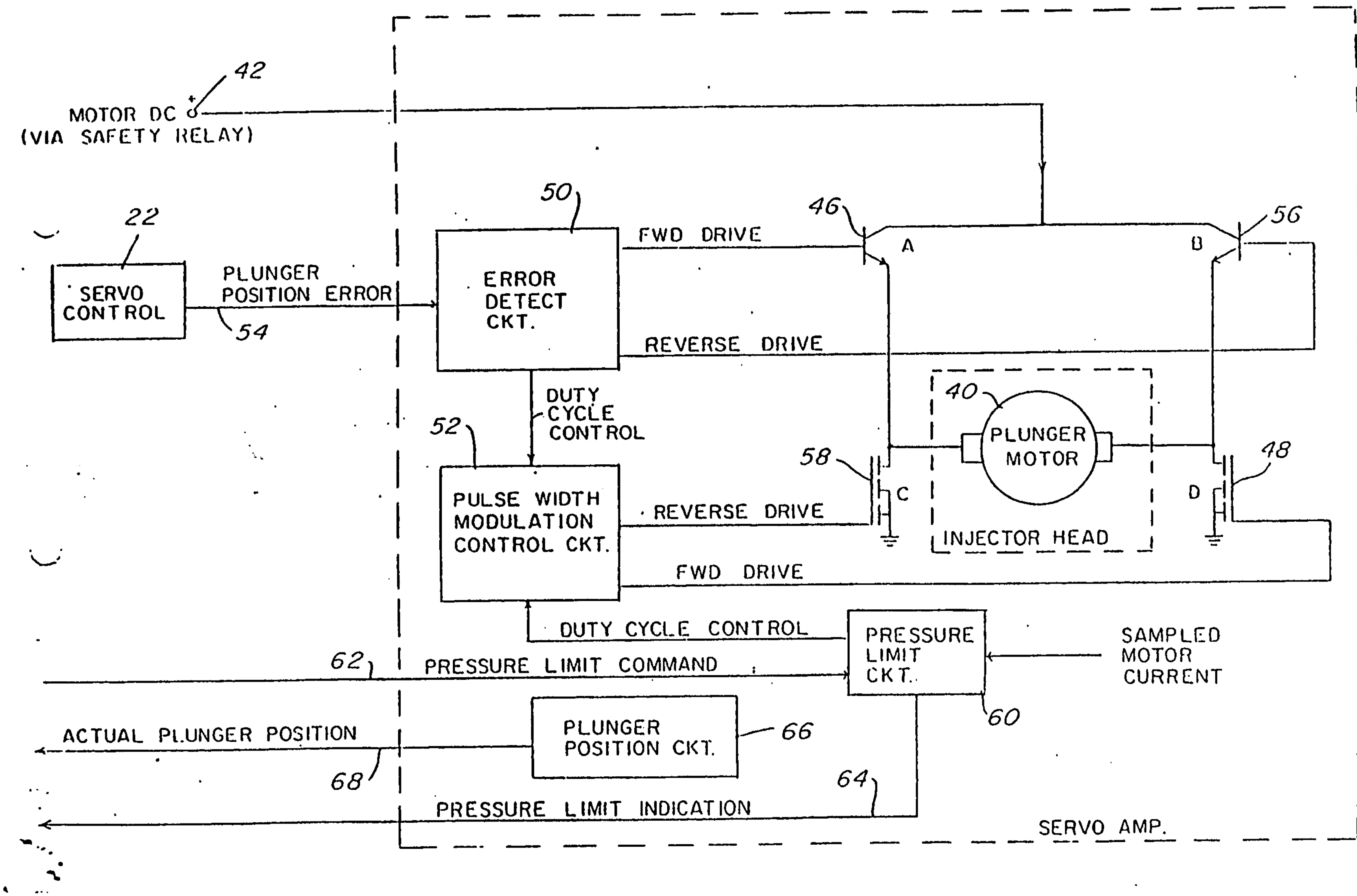


FIG. 2



42
MOTOR DC
(VIA SAFETY RELAY)
22
SERVO CONTROL
PLUNGER POSITION ERROR
54
50
ERROR DETECT CKT.
FWD DRIVE
REVERSE DRIVE
46
A
56
B
DUTY CYCLE CONTROL
52
PULSE WIDTH MODULATION CONTROL CKT.
REVERSE DRIVE
FWD DRIVE
58
C
40
PLUNGER MOTOR
INJECTOR HEAD
48
D
DUTY CYCLE CONTROL
PRESSURE LIMIT CKT.
60
SAMPLED MOTOR CURRENT
62
PRESSURE LIMIT COMMAND
PLUNGER POSITION CKT.
66
ACTUAL PLUNGER POSITION
68
64
PRESSURE LIMIT INDICATION
SERVO AMP.
24

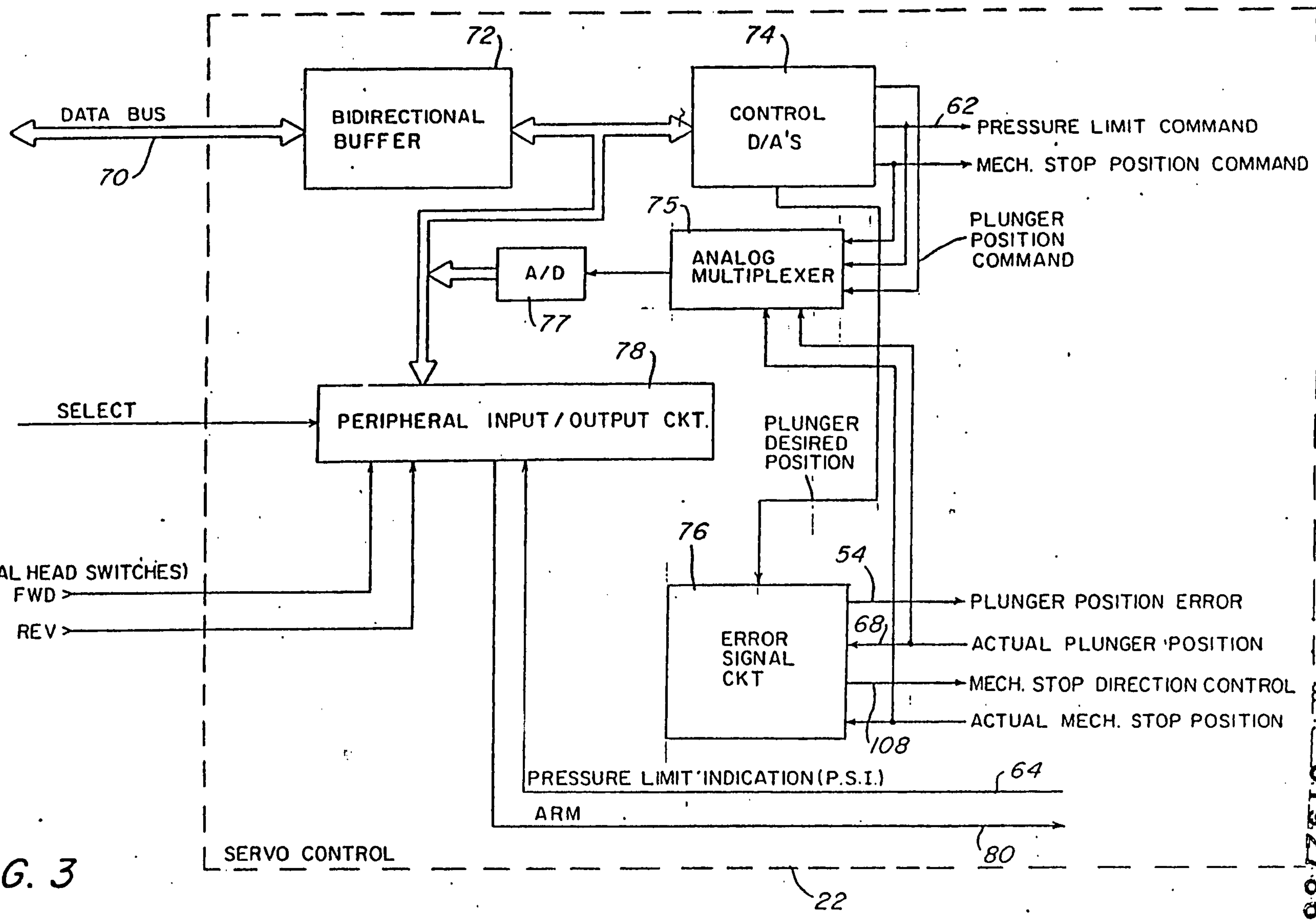

DATA BUS
70
BIDIRECTIONAL BUFFER
72
CONTROL D/A'S
74
62
PRESSURE LIMIT COMMAND
MECH. STOP POSITION COMMAND
PLUNGER POSITION COMMAND
ANALOG MULTIPLEXER
75
A/D
77
PERIPHERAL INPUT/OUTPUT CKT.
78
SELECT
PLUNGER DESIRED POSITION
ERROR SIGNAL CKT
76
54
68
108
PLUNGER POSITION ERROR
ACTUAL PLUNGER POSITION
MECH. STOP DIRECTION CONTROL
ACTUAL MECH. STOP POSITION
(MANUAL HEAD SWITCHES)
FWD
REV
PRESSURE LIMIT INDICATION (P.S.I.)
64
ARM
80
SERVO CONTROL
22

FIG. 3

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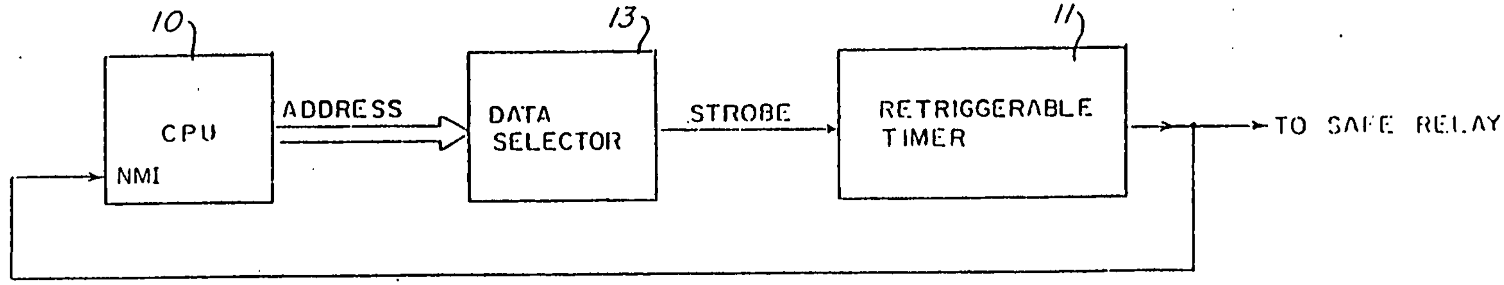
FIG. 1B



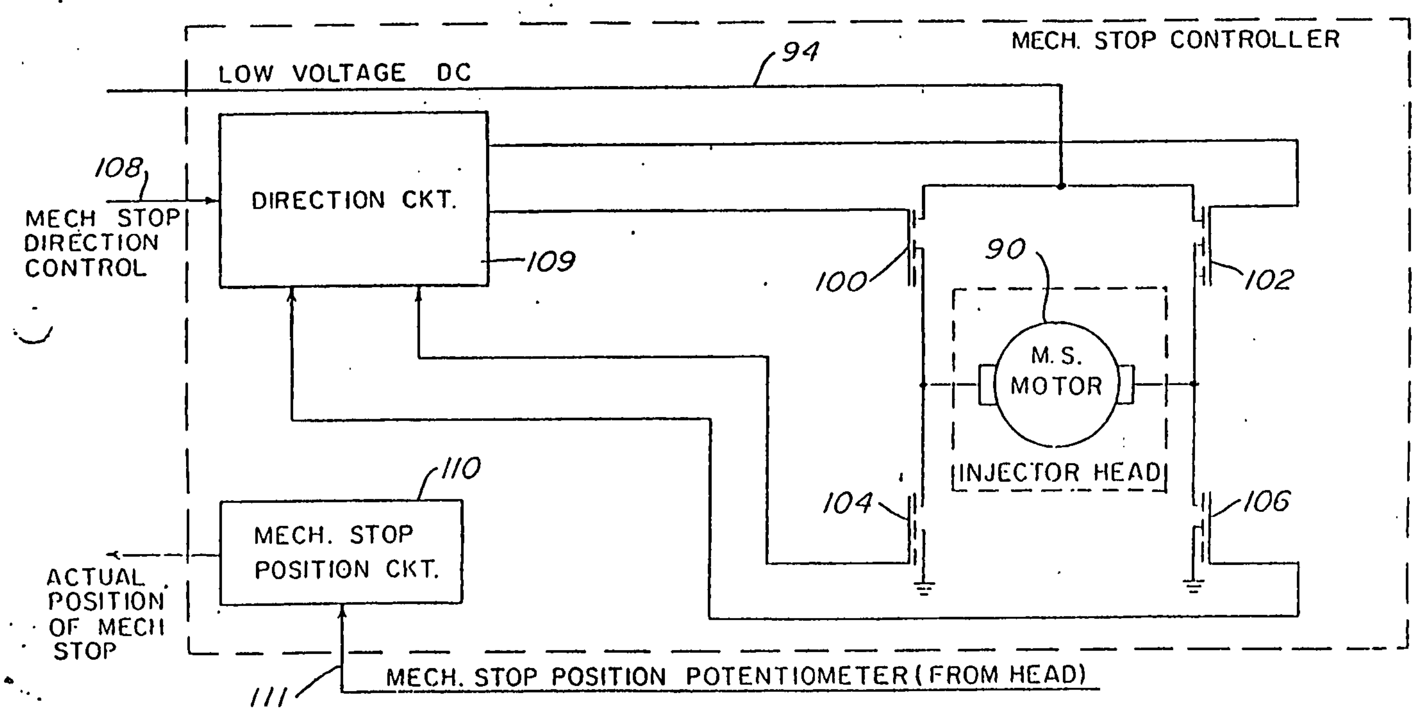


FIG. 4

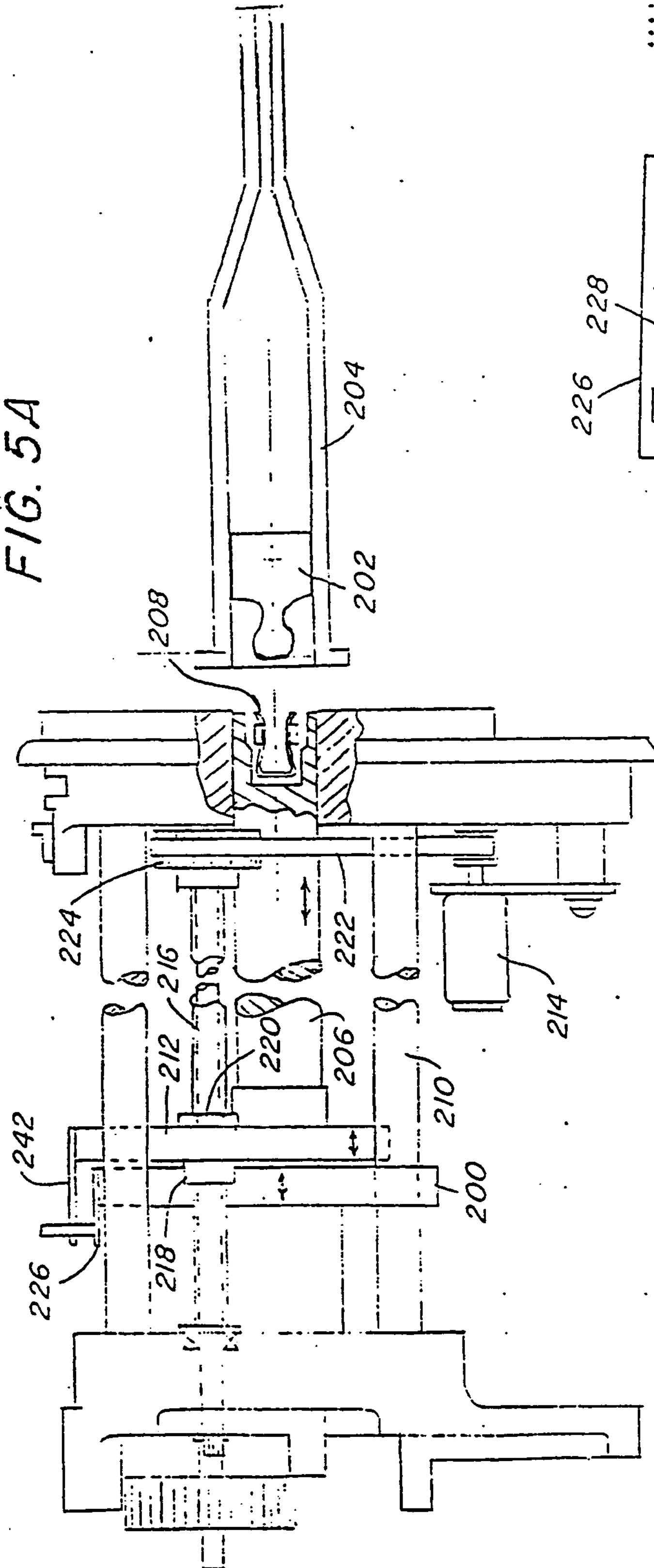

200
202
204
206
208
210
212
214
216
218
220
222
224
226
242

FIG. 5A

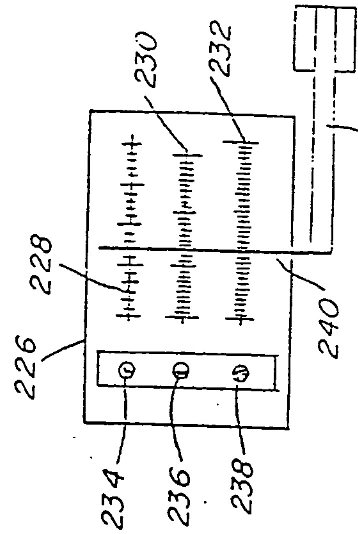

226
228
230
232
234
236
238
240
242

FIG. 5B

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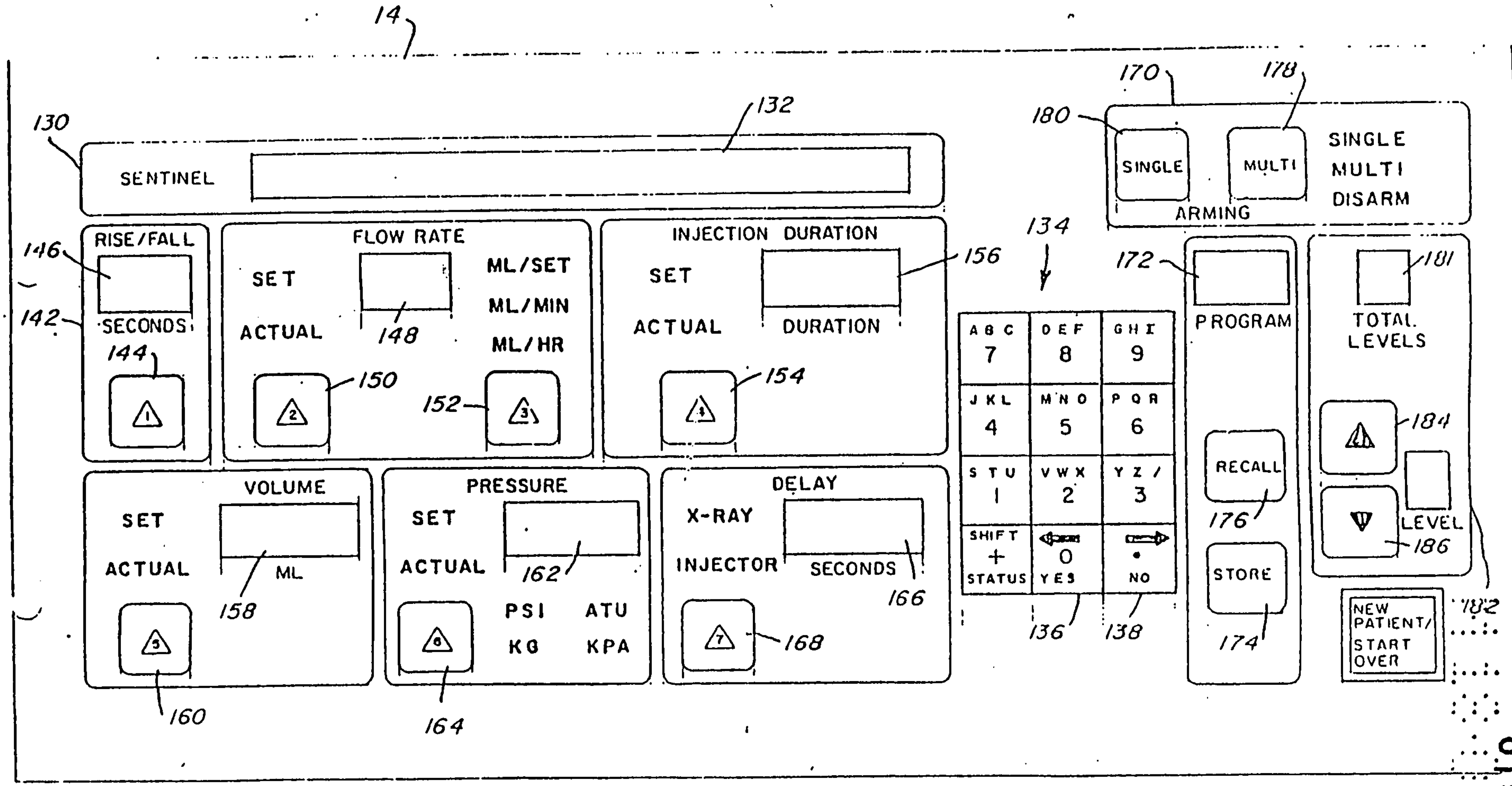


FRONT PANEL 14

FIG. 6

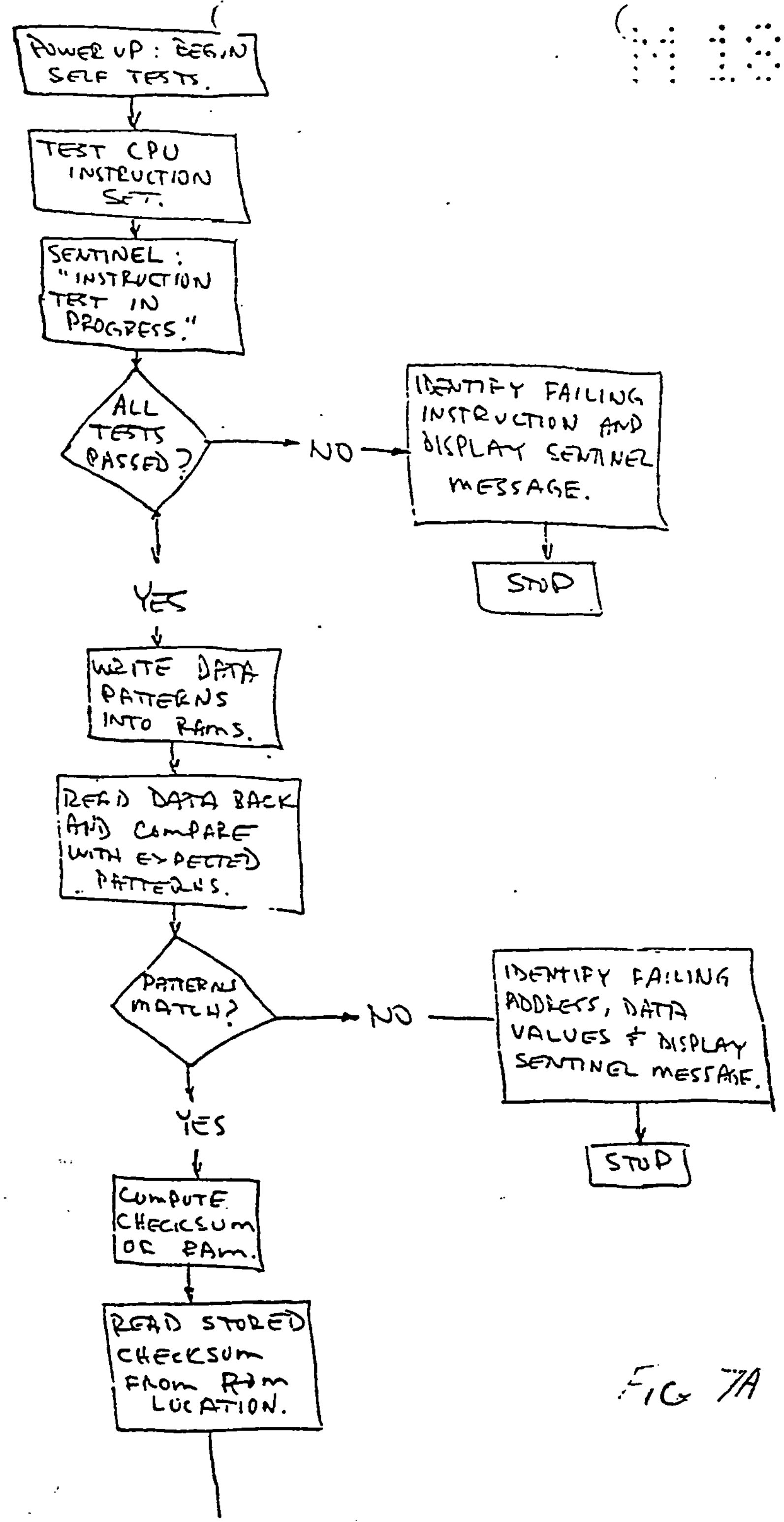
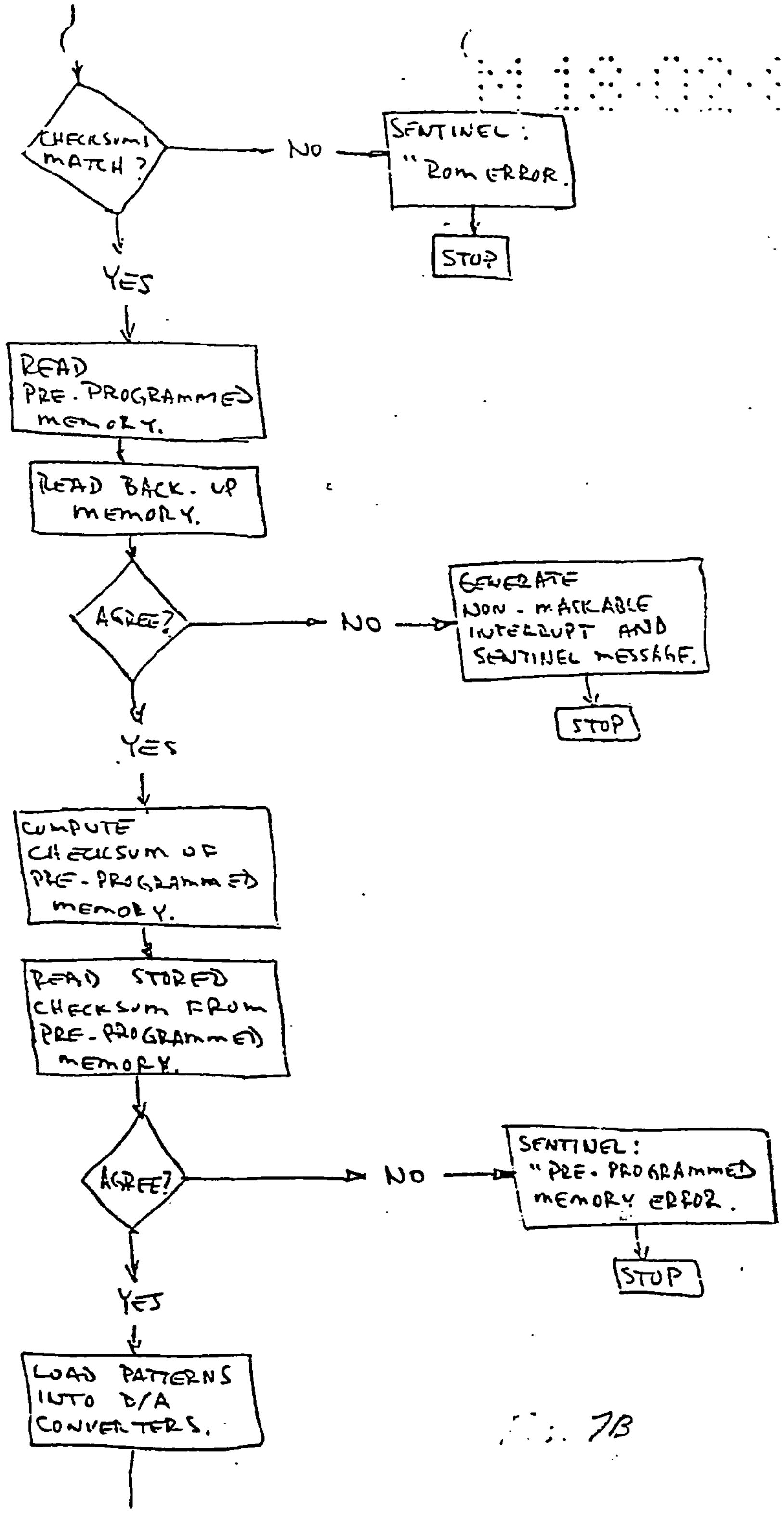

POWER UP: BEGIN SELF TESTS.
TEST CPU INSTRUCTION SET.
SENTINEL: "INSTRUCTION TEST IN PROGRESS."
ALL TESTS PASSED?
NO
IDENTIFY FAILING INSTRUCTION AND DISPLAY SENTINEL MESSAGE.
STOP
YES
WRITE DATA PATTERNS INTO RAMS.
READ DATA BACK AND COMPARE WITH EXPECTED PATTERNS.
PATTERNS MATCH?
NO
IDENTIFY FAILING ADDRESS, DATA VALUES & DISPLAY SENTINEL MESSAGE.
STOP
YES
COMPUTE CHECKSUM OF RAM.
READ STORED CHECKSUM FROM RAM LOCATION.

FIG 7A


CHECKSUMS MATCH ?
NO
SENTINEL : "ROM ERROR.
STOP
YES
READ PRE-PROGRAMMED MEMORY.
READ BACK-UP MEMORY.
AGREE?
NO
GENERATE NON-MASKABLE INTERRUPT AND SENTINEL MESSAGE.
STOP
YES
COMPUTE CHECKSUM OF PRE-PROGRAMMED MEMORY.
READ STORED CHECKSUM FROM PRE-PROGRAMMED MEMORY.
AGREE?
NO
SENTINEL : "PRE-PROGRAMMED MEMORY ERROR.
STOP
YES
LOAD PATTERNS INTO D/A CONVERTERS.

7B

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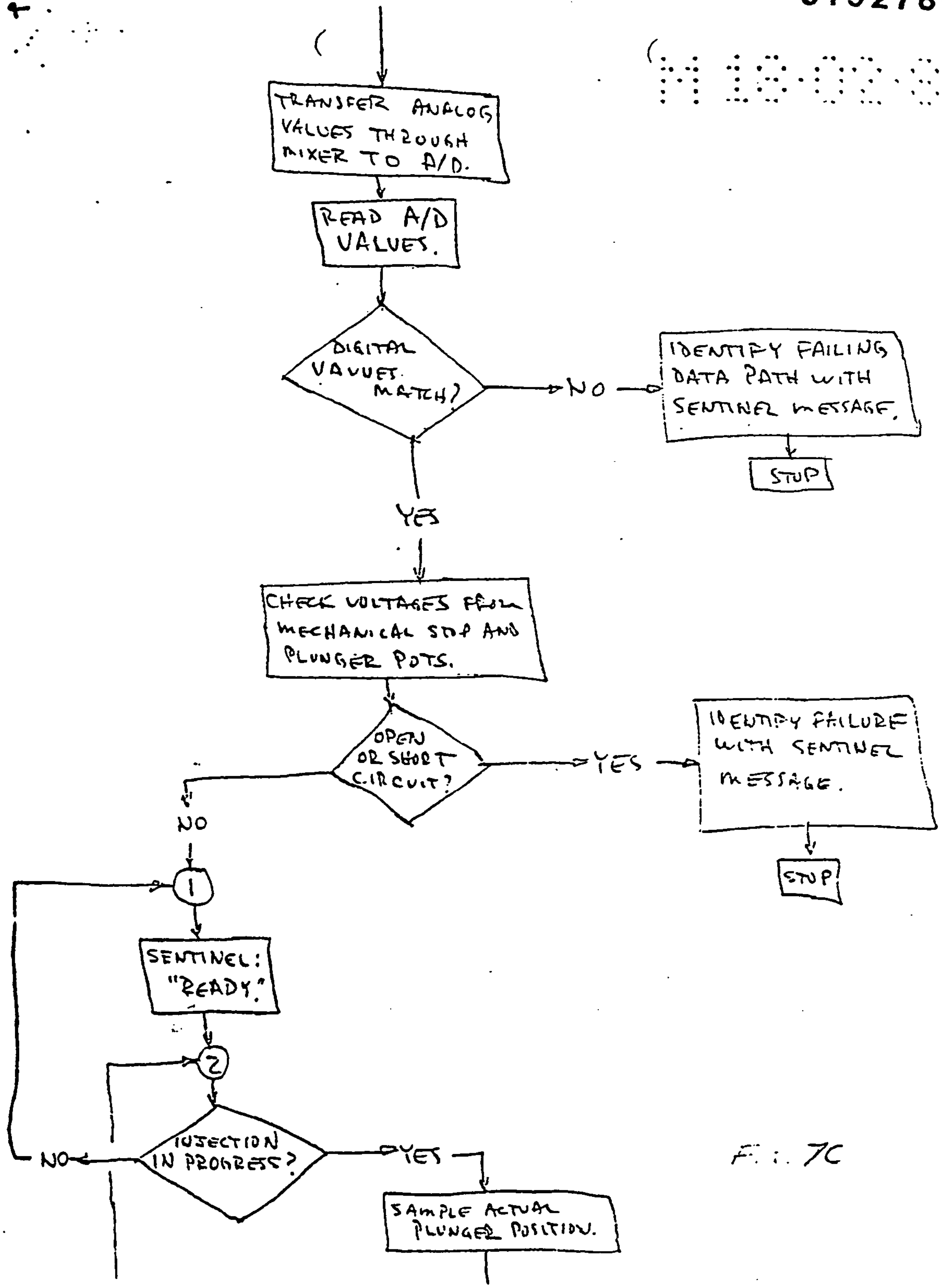
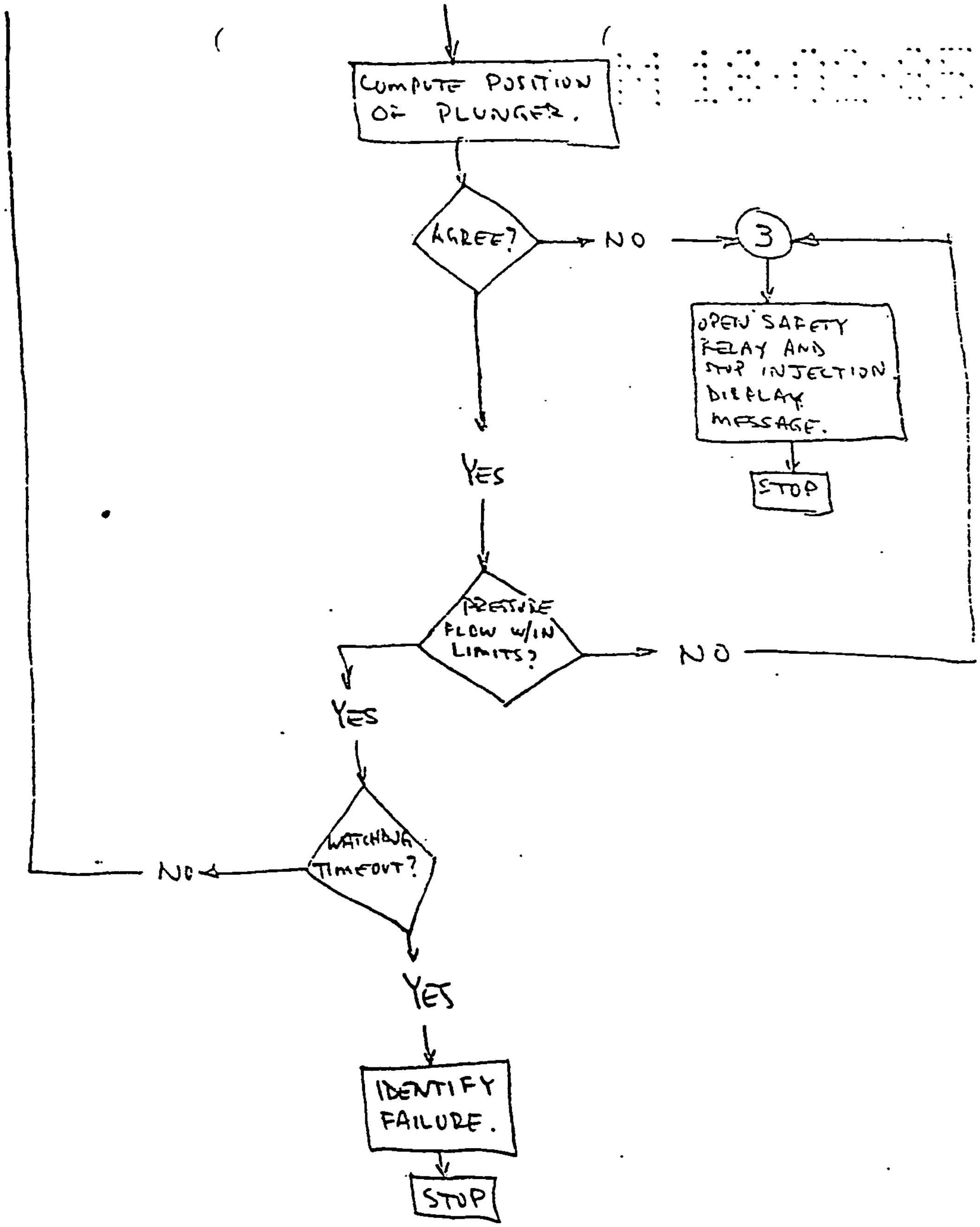

TRANSFER ANALOG VALUES THROUGH MIXER TO A/D.
READ A/D VALUES.
DIGITAL VALUES MATCH?
NO
IDENTIFY FAILING DATA PATH WITH SENTINEL MESSAGE.
STOP
YES
CHECK VOLTAGES FROM MECHANICAL STOP AND PLUNGER POTS.
OPEN OR SHORT CIRCUIT?
YES
IDENTIFY FAILURE WITH SENTINEL MESSAGE.
STOP
NO
1
SENTINEL: "READY."
2
INJECTION IN PROGRESS?
NO
YES
SAMPLE ACTUAL PLUNGER POSITION.

F: . 7C



COMPUTE POSITION OF PLUNGER.
AGREE?
NO
3
OPEN SAFETY RELAY AND STOP INJECTION. DISPLAY MESSAGE.
STOP
YES
PRESSURE FLOW W/IN LIMITS?
NO
YES
WATCHDOG TIMEOUT?
NO
YES
IDENTIFY FAILURE.
STOP

FIG. 7D

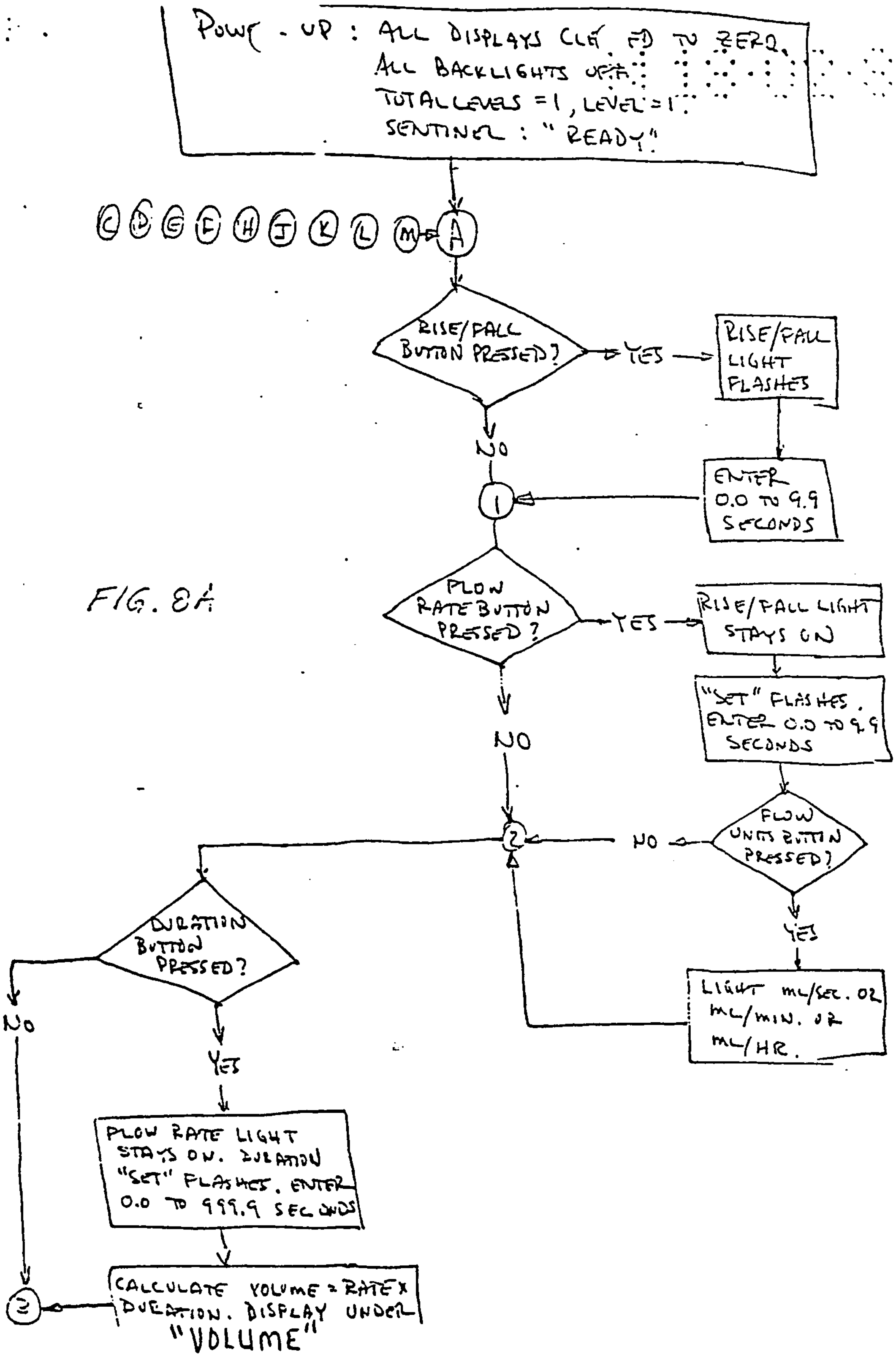

POWER-UP: ALL DISPLAYS CLEARED TO ZERO.
ALL BACKLIGHTS OFF.
TOTAL LEVELS = 1, LEVEL = 1
SENTINEL: "READY"
C D E F H J K L M A
RISE/FALL BUTTON PRESSED?
YES
RISE/FALL LIGHT FLASHES
NO
ENTER 0.0 TO 9.9 SECONDS
1
FLOW RATE BUTTON PRESSED?
YES
RISE/FALL LIGHT STAYS ON
"SET" FLASHES. ENTER 0.0 TO 9.9 SECONDS
NO
2
NO
FLOW UNITS BUTTON PRESSED?
YES
LIGHT ml/sec. OR ml/min. OR ml/HR.
DURATION BUTTON PRESSED?
NO
YES
FLOW RATE LIGHT STAYS ON. DURATION "SET" FLASHES. ENTER 0.0 TO 999.9 SECONDS
CALCULATE VOLUME = RATE x DURATION. DISPLAY UNDER "VOLUME"
3

FIG. 8A

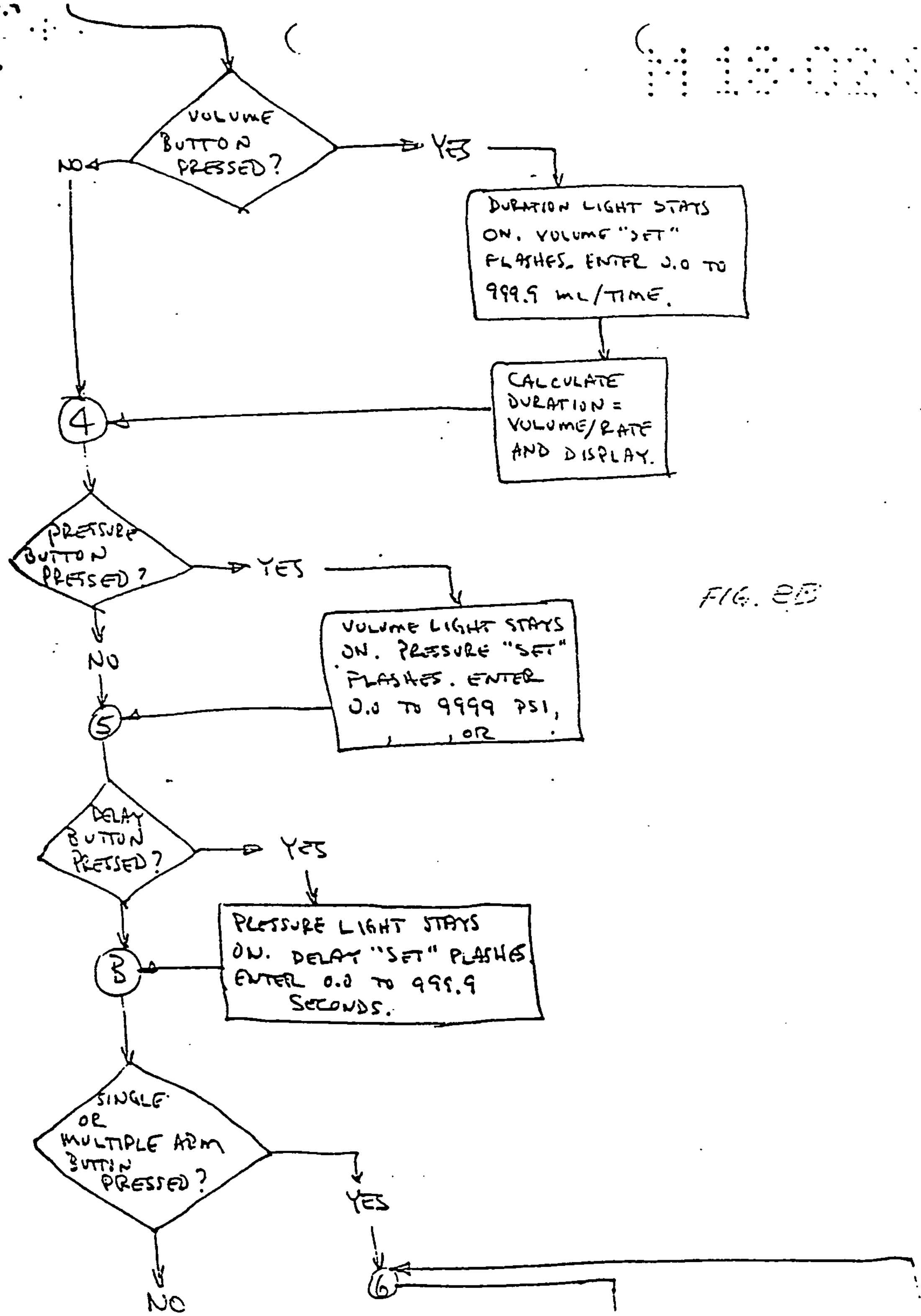

VOLUME BUTTON PRESSED?
YES
NO
DURATION LIGHT STAYS ON. VOLUME "SET" FLASHES. ENTER 0.0 TO 999.9 mL/TIME.
CALCULATE DURATION = VOLUME/RATE AND DISPLAY.
4
PRESSURE BUTTON PRESSED?
YES
NO
VOLUME LIGHT STAYS ON. PRESSURE "SET" FLASHES. ENTER 0.0 TO 9999 PSI, , , OR .
5
DELAY BUTTON PRESSED?
YES
PRESSURE LIGHT STAYS ON. DELAY "SET" FLASHES ENTER 0.0 TO 999.9 SECONDS.
3
SINGLE OR MULTIPLE ARM BUTTON PRESSED?
YES
NO
6

FIG. 8B

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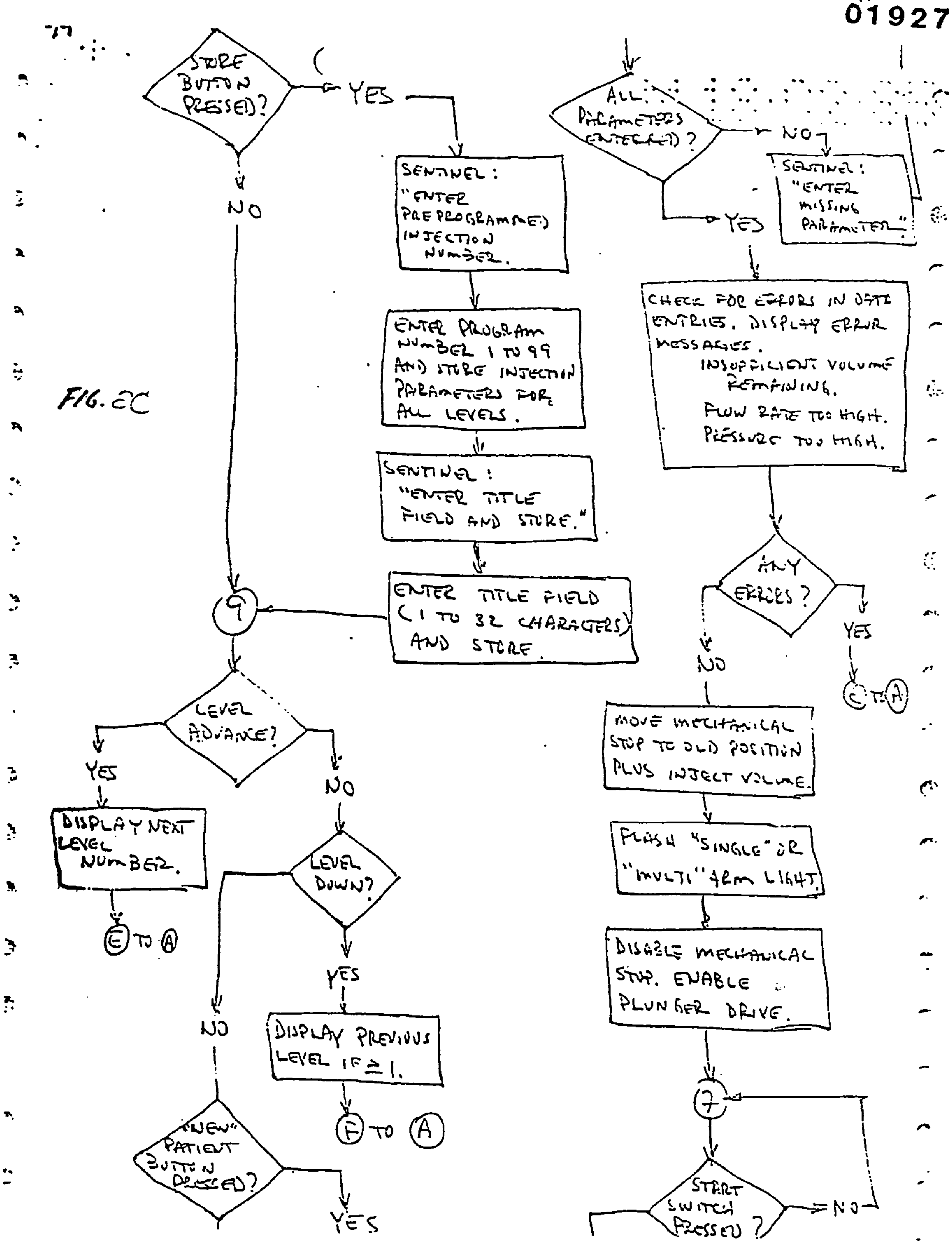

FIG. 8C

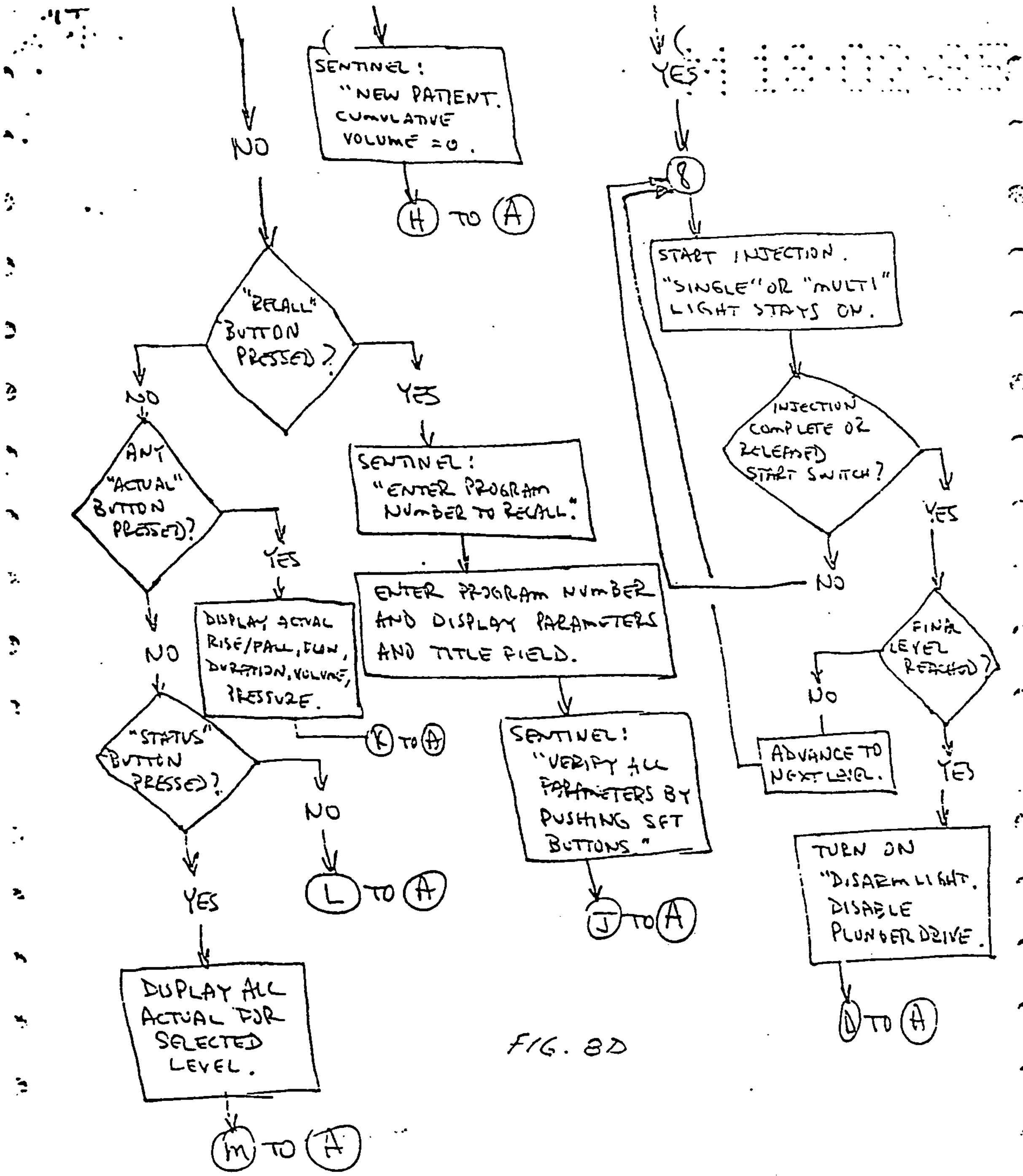
NO
SENTINEL: "NEW PATIENT. CUMULATIVE VOLUME = 0.
H TO A
YES
8
START INJECTION. "SINGLE" OR "MULTI" LIGHT STAYS ON.
"RECALL" BUTTON PRESSED?
NO
YES
INJECTION COMPLETE OR RELEASED START SWITCH?
YES
NO
ANY "ACTUAL" BUTTON PRESSED?
YES
SENTINEL: "ENTER PROGRAM NUMBER TO RECALL."
ENTER PROGRAM NUMBER AND DISPLAY PARAMETERS AND TITLE FIELD.
DISPLAY ACTUAL RISE/FALL, FLOW, DURATION, VOLUME, PRESSURE.
NO
FINAL LEVEL REACHED?
NO
K TO A
"STATUS" BUTTON PRESSED?
SENTINEL: "VERIFY ALL PARAMETERS BY PUSHING SET BUTTONS"
ADVANCE TO NEXT LEVEL.
YES
NO
TURN ON "DISARM LIGHT, DISABLE PLUNGER DRIVE.
YES
L TO A
J TO A
DISPLAY ALL ACTUAL FOR SELECTED LEVEL.
D TO A
M TO A

FIG. 8D